



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

(mu)

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 10/049,316 | 02/08/2002 | Ralph M. Steinman | 7529/1F590-US1 | 3722 |
| 7590 | 03/10/2004 | | EXAMINER | |
| Darby & Darby 805 Third Avenue New York, NY 10022-7513 | | | WORTMAN, DONNA C | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1648 | |

DATE MAILED: 03/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|--|-------------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/049,316 | STEINMAN ET AL. | |
| | Examiner Donna C. Wortman, Ph.D. | Art Unit 1648 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 12 December 2003.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-45 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) _____ is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) 1-45 are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____. | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____ |

Applicant's election of Group IV, claims 35 and 37-39, with traverse is acknowledged; however, on further consideration, the restriction requirement as previously presented is withdrawn and the following requirement is made in order to revise the groups, to include certain claims that were inadvertently omitted, and to expand the reasons for restriction.

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 1-4, 10, 11, 16 and 17, drawn to a vaccine comprising an immunogenic EBNA-1 polypeptide and an adjuvant, and a method of use of the vaccine.

Group II, claim 5-9, 12-15, 18, and 19, drawn to an expression vector for expression in humans comprising a sequence encoding an immunogenic EBNA-1 polypeptide and a method of immunizing using the expression vector.

Group III, claims 20-26, drawn to a pharmaceutical composition comprising an EBNA-1 charged dendritic cell.

Group IV, claim 27, 31, 32, and 34, drawn to a method for protecting a subject from infection by EBV comprising administering an EBNA-1 charged dendritic cell.

Group V, claim 28, 29, 30, and 33, drawn to a method for protecting a subject from EBV-associated malignancies comprising administering an EBNA-1 charged dendritic cell.

Group VI, claims 35 and 37-39, drawn to a method for making an EBV-protective human dendritic cell comprising contacting the cell with EBNA-1 *ex vivo*.

Group VII, claim 36, drawn to a method for making an EBV-protective human dendritic cell comprising contacting the cell with EBNA-1 *in vivo*.

Group VIII, claims 40-45, drawn to a method for making an EBV-protective human dendritic cell comprising contacting the cell with a vector for expression of EBNA-1 in humans.

The inventions listed as Groups I-VIII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The special technical feature of the main invention, i.e., the invention of Group I, is a vaccine comprising an immunogenic EBNA-1 polypeptide and an adjuvant acceptable for use in a human, and a method of immunizing a human using the polypeptide vaccine. The EBNA-1 polypeptide composition of Group I does not require the invention of Group II since EBNA-1 polypeptide can be purified from other sources, including *in vitro* cell cultures; thus the invention of Group I does not share a special technical feature with the invention of Group II. The invention of Group I does not share a special technical feature with any of the inventions of Groups III-VIII since the invention of Group I does not require a dendritic cell as claimed in Group III. PCT Rule 13 does not provide for multiple products, such as those of Groups II and III, nor for methods of making and methods of use of multiple products, as those of Groups IV-VIII.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i). Any inquiry concerning this communication or earlier communications from the examiner should be directed to Donna C. Wortman, Ph.D. whose telephone number is 571-272-0913. The examiner can normally be reached on Monday-Thursday, 7:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Donna C. Wortman, Ph.D.
Primary Examiner
Art Unit 1648

dcw